REMARKS

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Office Action asserted that "it is unclear if the recitation of the distance between the electrodes in the range of about 6 mm to 10 mm is supported by applicant's disclosure". However, Applicants respectfully traverse this rejection as follows.

Applicants submit that the Office Action improperly rejected claims 1-7 under the first paragraph of 35 U.S.C. § 112, because the Office Action does not set forth express findings of fact which support the lack of written description conclusion. See MPEP § 2163.04(I). According to MPEP § 2163.04(I), the Examiner must:

(A) Identify the claim limitation(s) at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

In the instant case, the Office Action has not satisfied element B of the requirement set forth in MPEP § 2163.04(I). In particular, the Office Action merely asserted that the "specification only appears to disclose the broader range of 2 mm to 10 mm, ¶0026, not the more narrow range of 6 mm to 10 mm". In other words, the Office Action has merely presented

an insufficient conclusory statement to improperly reject claims 1-7.

Furthermore, the Office Action does not provide reasons why a person skilled in the art would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure as filed. The Office Action cannot provide such reasons, because the specification clearly states (as admitted by the examiner) "The distance between the two electrodes of the probe should be about 2-10 mm". See paragraph [0026] of the Patent Application Publication. A person skilled in the art would understand that a range between about 2 mm to 10 mm includes at least any range between 2 mm and 10 mm. **For example, a person skilled in the art would understand that about 2 to 10 mm includes 3 to 10 mm, 4 to 10 mm, 5 to 10 mm, 6 to 10 mm, 7 to 10 mm, 8 to 10 mm, 9 to 10 mm, among numerous other ranges between about 2 to 10 mm.**

The examiner is further directed to MPEP §2165.05 III which states that "[i]n the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and ... **a limitation to "between 35% and 60%" did meet the description requirement**" [emphasis added].

Therefore, in view of the above, a person of ordinary skill in the art would readily appreciate that a "distance between two electrodes of the probe ... the said distance is about 6 mm to about 10 mm" (claim 1) is supported in the specification through implicit disclosure. Applicants note that MPEP §

2163(I)(B) does **not** require **in haec verba,** but instead **requires** that the limitations added be supported in the specification through express, **implicit,** or inherent disclosure (emphasis added). Because the MPEP does not require explicit support in the specification, the implicit disclosure of "about 6 mm to about 10 mm" satisfies the written description requirement under the first paragraph of 35 U.S.C. § 112.

Additionally, applicants submit that independent claim 7 recites "the said distance is about 2-10 mm" (and does not recite about 6 mm to about 10mm). It appears that the examiner intended to state that claims 1-6 were rejected under 35 U.S.C. §112, first paragraph. However, if the examiner intended to reject claim 7 under 35 U.S.C. §112, first paragraph, applicants request further clarification.

Accordingly, Applicants respectfully request that the rejection of claims 1-7 be withdrawn for at least the reasons stated above.

The examiner is further directed to MPEP §2163.06 I which states that the "examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by applicant". It appears that the examiner has not done this in this case.

Claims 1, 2, and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of Measurement of Dielectric Properties of Subcutaneous Fat with Open-Ended Coaxial Sensors by Esko et al.("Measurement").

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of "Measurement" and Sherwin (US 4,640,290). Claims 5-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of "Measurement" and Penetration of Electromagnetic Fields of an Open-Ended Coaxial Probe between 1 MHz and 1 GHz in Dielectric Skin Measurements by Esko et al. ("Penetration"). Claims 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Malicki et al. (US 4,918,375) in view of "Measurement" or "Penetration" or Campbell et al. (US 6,370,426). The examiner is requested to reconsider these rejections.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Claim 1 claims, *inter alia*, a method for measuring tissue edema wherein "a distance between two electrodes of the probe being large enough in order for the electronic field to penetrate up to the subcutaneous fat tissue, and the said distance is about 6 mm to about 10 mm". Claim 1 further claims "an electromagnetic probe is placed on the skin during the measurement, and a capacitance of the probe is proportional to a dielectric constant of the skin and subcutaneous fat tissue, which is further proportional to a water content of the skin".

Applicants submit that edema, as described in the application (for example see page 1, lines 3-14), is an abnormal

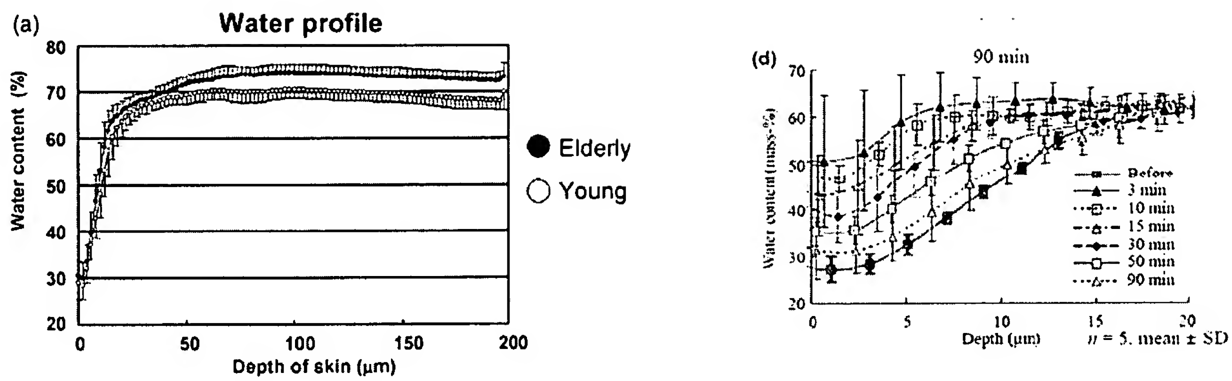
accumulation of fluid beneath the skin or in one or more cavities of the body. Generally, the amount of interstitial fluid is determined by the balance of fluid homeostasis, and increased secretion of fluid into the interstitium or impaired removal of this fluid may cause edema (see Edema. (2010, February 18). In Wikipedia, The Free Encyclopedia. Retrieved 21:43, March 10, 2010, from http://en.wikipedia.org /w/index.php?title=Edema&oldid=344747493). Hence it can be said that tissue fluids that provide affects on edema are movable part of fluids. These fluids are called interstitial fluid.

Applicants submit that in the multilayered skin structure there are water molecules in the skin surface. The water molecules are coming to skin surface due to a diffusion process from air or from lower dermal part of the skin (called dermis). The resulting moisture is generally called skin surface hydration. Since there is no blood circulation or lymph vessels in the skin surface, edema in skin surface is impossible but possible in dermis due to a rich vascular network. Campbell merely discloses a method and an apparatus for measuring skin surface hydration mainly interested by the cosmetic industry. Skin edema described by the applicants is merely related to medicine and biological applications with abnormal accumulation of movable tissue fluid into skin structures other than skin surface.

For further clarification, applicants include the additional description of the skin, its structure and contribution to edema in more detail.

Skin is a layered structure. Therefore, it is important to specify the structure that one is discussing. The uppermost layers are stratum corneum (thickness only about 0.02 to 0.04 mm) and epidermis (thickness about 0.07-0.15 mm). Together they form an epidermal barrier. The epidermal barrier does not contain blood vessels. Therefore, the tissue water in the epidermal barrier is determined by humidity of ambient air and diffusion of water molecules from layers below the epidermal barrier. Since ambient air has low amount of water but deeper structures of the skin have plenty of tissue water, the epidermal barrier has a water concentration gradient from 30 to 70 weight-% (Figure 1a, see below). The water gradient is a result of a balance where more water is escaping from the skin surface than is coming from deep skin structures by diffusion to the skin surface. Although stratum corneum is very thin its structure forms an efficient barrier to prevent water to escape from body and protect penetration of external substances into skin. Since water content in the epidermal barrier is regulated by diffusion from outside and inside structures, it can have increased or decreased hydration but no edema. This is illustrated in Figure 1b (see below) where increased hydration of skin surface (i.e. epidermal barrier) exits due to the 90 min wetting of skin with soaked cotton wool. In Figure 1b the lower curve 'Before' jumps up (black triangles) and returns back to basic level in 90 min after removing the soaked cotton wool.

Figure 1a, 1b:



a)

b)

Figs. 1a/1b: 1a) Typical water profile of human stratum corneum from 0 to 0.2 mm measured by Raman spectroscopy (from Nakagawa et al, 137-141,16:2010, Skin Research and Technology) 1b) Differences in the depth profiles of water content in the forearm skin before and after hydration with water soaked cotton wool for 90 minutes (from Byrne AJ, Int. J. Cosmetic Sci. 32,pp.410-421, 2010)

This example simulates the condition when the skin surface (i.e. the first 15 micrometers) has first low hydration and followed by wetting induced high hydration.

Cells in the epidermal barrier region are renewed every two weeks. After maturation the cells gradually move towards the skin surface before final desquamating from the skin surface. If the skin experiences trauma (for instance wound or excessive dosage of sunshine) the skin surface can become very moisture due to the increased diffusion of water into the skin surface. Still there is no edema in the skin surface (although

there might be an edema under the epidermal barrier due to the trauma.

To describe more the effect of skin barrier function we can examine friction-induced blister where tissue fluid is collected under epidermis. Epidermal barrier prevents tissue fluid leakage out of skin. In blister itself a huge accumulation of tissue fluid might exist but the surface of the skin over the blister has normal hydration. The situation again simulates edema: skin surface has normal hydration and edema appears in deeper skin structures. **In conclusion, in stratum corneum and epidermis consisting of epidermal barrier edema has never been detected.**

Beneath stratum corneum and epidermis, i.e. epidermal barrier lies dermis. Dermis can be subdivided into the superficial papillary dermis and deeper and thicker reticular dermis. The thickness of dermis is typically 10-30 times the thickness of epidermal barrier and varies from about 1 to 3 mm. The dermis is composed of collagen fibers, elastic fibers and so called ground substance (so-called proteoglycans). These dermal structures can bind a huge amount of tissue water due to their surface charge. The dermis is thus one of the largest water reservoirs of the body. Dermis also has rich vascular network (see Figure 2 below) that is responsible for nutrition of dermal cells. High water binding capacity and rich vascular network of dermis are reasons why the accumulation of tissue fluid in dermis is possible. **It means that edema can appear in dermis.**

Figure 2:

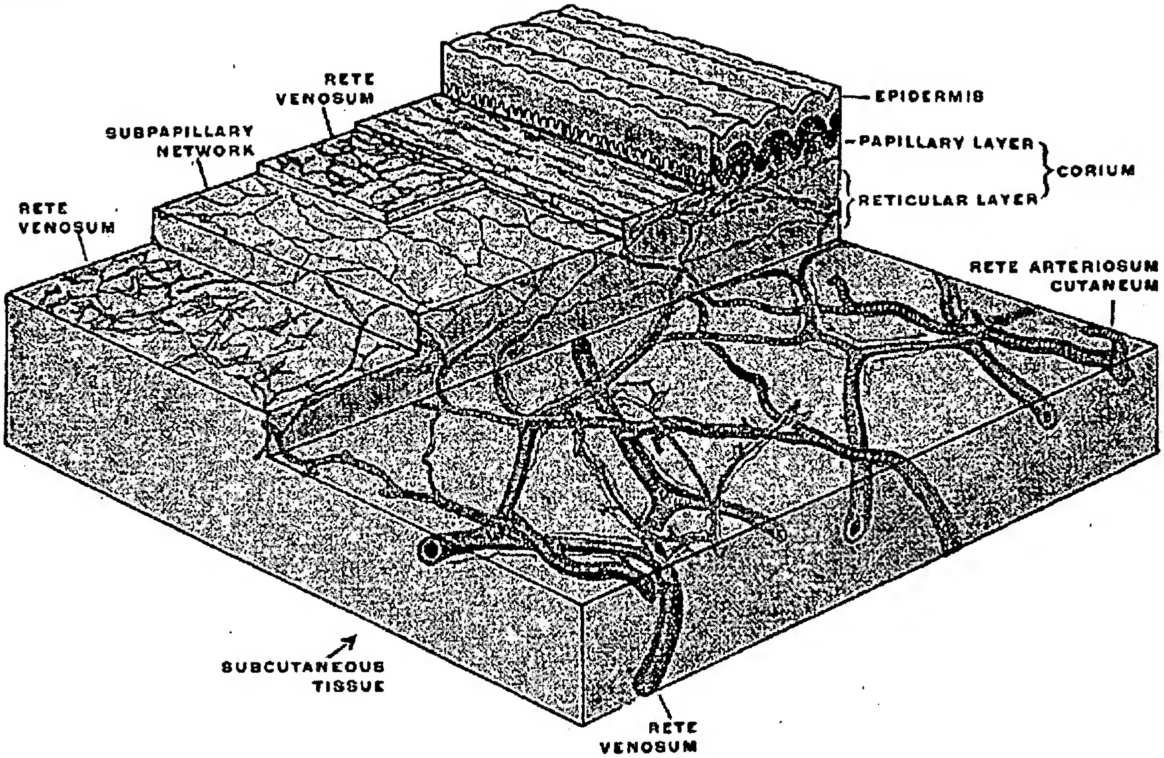


Figure 2. Rich vascular network can be found in dermis and subcutaneous fat but not in the surface of skin (epidermis).

Beneath dermis is so-called hypodermis, which is also known subcutis or subcutaneous fat. This tissue consists of fat cells. The subcutaneous fat water content is about 10-20 weight-%. Since vascular networks of subcutaneous fat and dermis are partly common, the edema in one tissue component appears also in the other.

These many examples together with the described structure of **skin anatomy determine that edema can occur deeper in skin but not in superficial, i.e. epidermal barrier region. This physiological background sets requirements for the technique**

of the edema measurement. Figure 3 (see below) summaries different skin structures and their contribution to edema.

Figure 3:

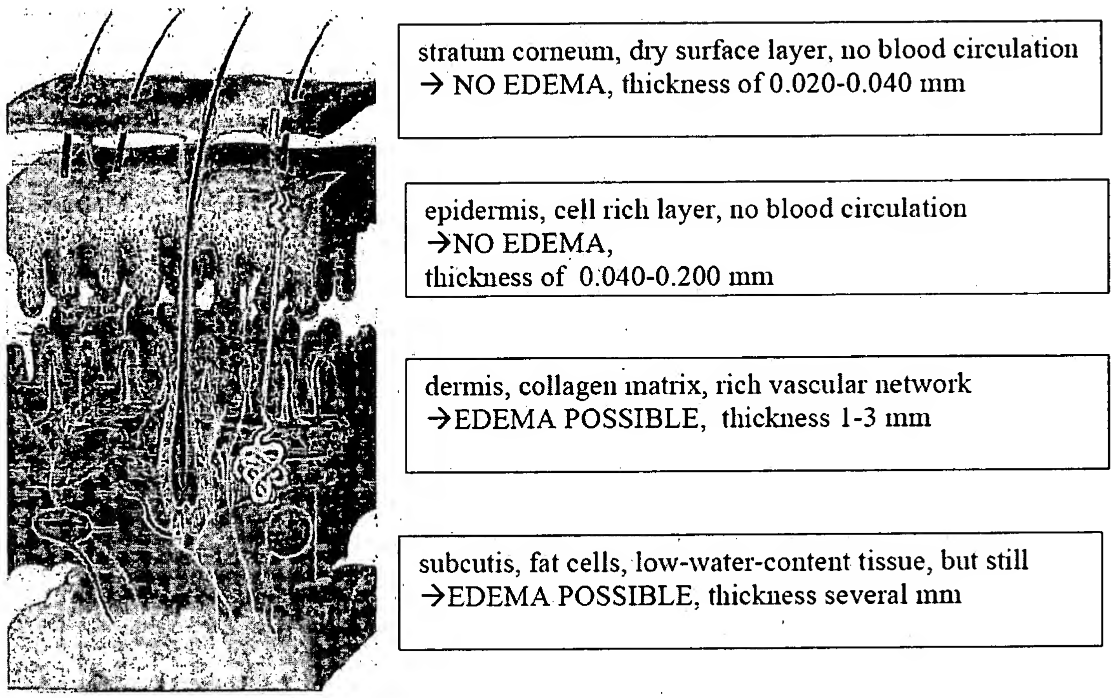


Figure 3. Schematic skin layers [source of colour picture: bioartskincare.com] (not in scale). Skin consists of different layers and they have different amount of water.

In addition to origin of edema also the methods that have been presented to detect edema need some clarifications. Some of the methods described below cannot be used to detect edema simply because the measurement fields applied in these techniques are not penetrating deep enough, i.e. into the region where the edema appears.

Campbell merely discloses a method and an apparatus for measuring relative hydration of a substrate. The force applied to and the temperature of the substrate during the measurements is used to ensure proper results of relative hydration. Campbell teaches that the invention can also be used to measure skin by stating that substrate means also skin. (Col 3, rows 28-29). However, Campbell does not specify which layered structure they mean with a term "skin". **As described earlier skin is not a homogeneous tissue and all anatomical layers of skin do not contribute edema at all.** Throughout the whole document of Campbell, a term of relative hydration is used. It is measured in sense of impedance and to be more specific capacitive reactance is measured that is said to be an indicator of substrate moisture (Col 4, rows 62-65). However, Campbell does not specify any SI-units of the readouts of the method. Since the method is said to measure relative hydration, the method does not give absolute values for the hydration.

Campbell **does not disclose anything about measuring edema.** The examiner states that Campbell discloses that a capacitance of the probe is measured to measure the skin water content or edema. Applicants respectfully disagree with the examiner. Applicants submit that if one skilled in the art were to measure substrate moisture or substrate hydration [as disclosed in Campbell at Col. 1, lines 16-17, and Col. 4, lines 49-65], **this would not mean that they can also measure edema.** This is because edema is a symptom that appears in deeper skin tissue **not on the skin surface** (skin surface can be determined as stratum corneum which forms the first tens of

micrometers of skin). Applicants' present application discloses the deeper origin of edema, for example see page 3, lines 1-11. In particular, it is described that the "skin becomes thicker as the edema increases and the fat tissue moves further from the probe..." (see page 3, lines 8-9). This describes that edema is found in deeper skin tissue and hence it is impossible to detect by measuring just the superficial part of the skin. Support for this can be found in the present application at page 3, lines 12-16 where it is said "...electric field is concentrated on the superficial layers of the skin and the measurement of edema is not possible." Therefore, applicants submit that skin surface (**i.e. epidermal barrier**) hydration that is measured by the method and probe described by Campbell has nothing to do with edema detection. Hence, and as described also above, the edema cannot be found in the skin surface.

Instead, Campbell describes a method to measure relative hydration or relative moisture. These terms 'hydration' and 'moisture' are **irrelevant** when compared to the term 'edema', which is massive tissue fluid accumulation in tissue. Applicants' present application discloses that edema means accumulation of extra water in soft tissue and it leads increase in tissue volume (for example see Page 1, lines 3-14). In tissue edema affecting dermal skin and subcutaneous fat tissue water is thus movable while at (horny) skin surface there is no movable water and thus no edema. Applicants further submit that the terms moisture and hydration are generally only used when very superficial phenomena are described.

In conclusion, applicants submit that Campbell merely teaches measuring skin surface hydration, and **provides no teaching relating to tissue edema**. Hence applicants respectfully disagree with the examiners opinion that although the term "substrate hydration" could be included the definition of edema it is not possible that Campbell would provide a method for measuring tissue edema. **Campbell cannot detect edema since edema itself cannot be found in the region that apparatus of Campbell measures**.

The dielectric properties like conductivity and permittivity change with EM-frequency. In the current application a physical permittivity-related quantity called a dielectric constant is measured. It has a nature constant value of 80 for pure distilled water at 20 Celcius temperature. Based on the definition: "Dielectric constant - for a given substance the ratio of the capacity of a condenser with that substance as dielectric to the capacity of the same condenser with a vacuum for dielectric" dielectric constant has a value of 1 for free space (vacuum and air) [Handbook of Chemistry and Physics, CRC Press, Boca Raton, FL, 1987].

In all tissues as with skin, the dielectric constant changes as a function of frequency. This phenomenon is called dispersion and it is caused by the different relaxation processes in the tissue when external electro-magnetic field is applied in tissue.

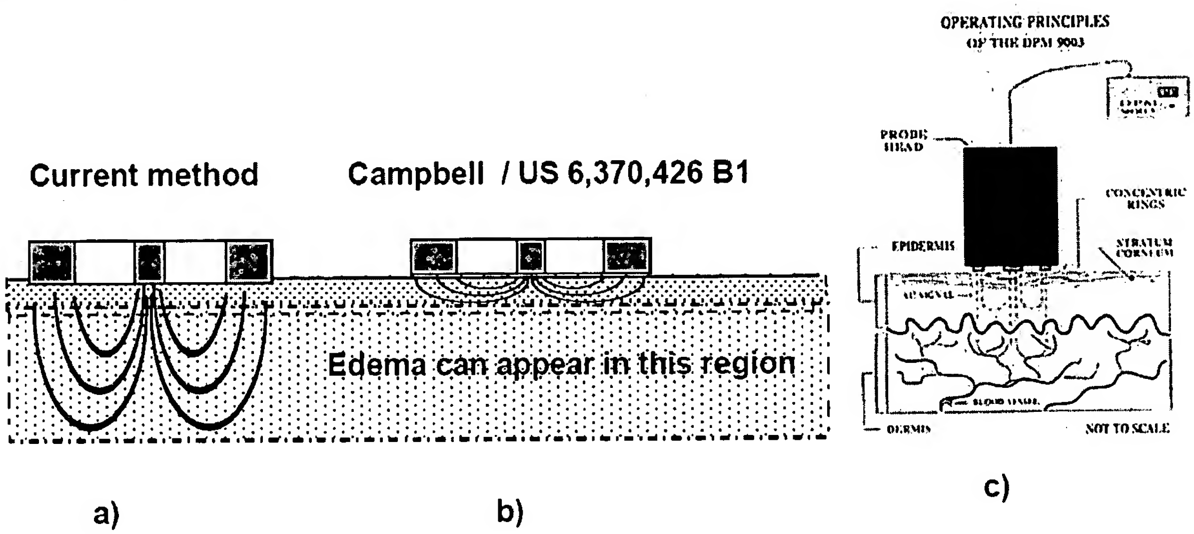
In practise the relaxation processes mentioned above mean that value of tissue dielectric constant of biological tissue changes from value of several tens of thousands at 1 kHz to

values of 20-60 at high radiofrequency like 300 MHz. Since at 300 MHz the dielectric constants of all other biological structures are low (5-10) and that of tissue water high (80), the measurement of tissue water with the applicant's electrical method is possible. Similar situation occurs also when a high electromagnetic frequency like 20-500 MHz is applied. The relation between amount of tissue water and dielectric constant at 300 MHz is shown in Figure 3 in the current Patent application. The development of edema (i.e. increase of dielectric constant from 35 to 52) in pig skin was induced by local blocking of venous outflow. At edematous site dielectric constant is increased over 40% when compared to the baseline values (varying between 30 and 36) at control sites with no edema.

Figures 4a, 4b, 4c (see below) illustrate the measurement depth of the applicants' and Campbell's methods. In figure 4a) the electric field of applicants' method penetrates into deeper skin structures through the stratum corneum and epidermis for edema detection. Instead Figures 4b) and 4c) (adopted from webpage of Nova Technology Corporation [http://www.novatechcorp.com/dpm.html, Jan 12th, 2011] illustrate the method (NOVA™ DPM 9003, Nova Technology Corporation, Gloucester, MA, US) that is based on the Campbell's patent. More direct evidence and support for the findings that Campbell patent-based Nova's technology really measures only superficial part of skin (stratum corneum and epidermis) can be found in US Patent 7,297,123 B2 (Col 2, rows 38-39) where Campbell admits that apparatus like his patent-based DPM (Dermal Phase Meter) provides measurement results "by means of

the measurement of *surface moisture*". Moreover, Campbell teaches more that "DPM apparatus have been used to make measurements of the capacitive reactance of skin" (US Patent 7,297,123 B2 (Col 2, rows 53-54) this is equivalent with the description of the Campbell's another Patent US 6,370,426 B1 documents (Col 4, rows 62-65) where "the result is a measurement of the complex impedance with a quantification of the capacitive reactance". This finding is direct evidence that Campbell's methods are not able to measure deeper phenomena in the skin like dermal/hypodermal edema.

Figure 4a, 4b, 4c:



<u>Figs. 4a, 4b, 4c.</u> Schematic representation of electric field in epidermis and dermis for a) current patent application method, and b) a method based on Campbell US patent 6,370,426 B1 c) an illustration adopted from Nova Technology Corporation webpage. Edema appearing in the deeper part of the skin (dermis) can be measured by the applicant's method but not with Campbell's method where the measuring electrical fields

reach only the superficial parts of skin (stratum corneum and epidermis). Not in scale.

Furthermore, the examiner admits that Campbell does "not disclose the capacitance of the probe as proportional to the dielectric constant of the skin and subcutaneous fat tissue and proportional to the water content of the skin, and is silent to the frequency used, and the size of the probe". Another essential difference between the applicants' claimed invention and Campbell is that Campbell does not describe anything about the used frequency of electromagnetic field that, in addition to the probe dimensions, also effects on the measuring depth of the method. As claimed in applicants' claimed invention (and as disclosed throughout the present application, see for example, page 4, lines 5-9), the probe dimension has an essential influence on the measuring depth.

The article "Measurement" is a theoretical study to research how dielectric constant of subcutaneous fat can be calculated. In the article there is no impression or use of term edema. The method applies so called three layer model, consisting of skin's superficial part stratum corneum, epidermis/dermis and subcutaneous fat. Furthermore, the model requires using three different size probes to calculate dielectric constant of subcutaneous fat (see abstract of "Measurement"). Hence the purpose of the "Measurement" is to describe a method how to measure dielectric constant of the subcutaneous fat. In the study, the frequency of 300 MHz was applied to test the model after radiation-induced late skin injury which is called subcutaneous fibrosis (see Introduction, last sentence, page 476). Applicants emphasize that **there is no mention of**

measuring tissue edema at all in the article. Furthermore, applicants submit that the purpose of applicants' claimed invention is not take subcutaneous fat into account which means determining of dielectrical values of the fat. Instead, applicants' claimed invention is directed to measure the whole volume seen by the probe and hence detect tissue edema. These are different scopes between the article Measurement and applicants' claimed invention.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. This phenomena is thought to be known as such and it can also be found in the current application where it is stated that "These kinds of methods are used to measure the dielectric properties of tissue which are proportional to the water of tissue" (see page 2, lines 11-14).

Table 1 (see below) summarizes key factors and differences between applicants' and Campbell's invention. The EM frequency must be selected properly to ensure that tissue water at the intended depth can be measured. The dimensions of the probe must be specified and adjusted so that measurement depth is deep enough into the skin layers where edema appears. Measurement quantity has to be selected so that the system really measures signal originating from water molecules and their total amount.

Table 1:

	Current application	Cambell
Applied measuring frequency of electromagnetic (EM) field. ❑ It's very important to select EM-frequency properly for measuring water (and thus edema). ❑ With improper frequency selection many other substances are measured instead of water	300 MHz	N/A No Teaching
Dimensions of the measuring probe, i.e. distance between inner and outer electrode ❑ Separation has to be proper for measuring deep enough	Specified to be deep enough to detect tissue edema	N/A No Teaching
Measuring quantity and its unit	SI Unit-related quantity, dielectric constant	Arbitrary and relative

Table 1. Comparison of current application vs. Campbell's method.

Applicants submit that the article Measurement does not disclose that measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use of three probes is a clear difference when comparing to applicants' claimed invention (where is no reference to using different size probes at the same time).

Applicants submit that the reason for using 300 MHz is addressed in the Discussion chapter where it is stated that at 300 MHz free and water bound to macromolecules has about the same value of dielectric constants (see "Measurement" Discussion page 483, second paragraph). Furthermore, **there is no mention in the article that these measurements are used to detect edema.**

The examiner also argues that Measurement "teaches … a larger probe (10 mm)", however, the probe dimensions mentioned in the article "Measurement" require some clarification when compared to the dimensions referred in the current application. Briefly the dimension "2-10 mm" mentioned in the previously presented form of claim 1 is the same as (b-a) in the Figure 1 in page 476 of Measurement. The distance between electrodes (b-a) affects on the measuring depth of the probe. Hence the so called probe '10mm' in the article "Measurement" has a dimension (b-a) value of 3.5 mm. Respectively, the dimensions of the other probes used in the article were 1.8mm (for the

probe '5mm') and 5.3 mm (for probe '15mm') see top of the page 479 and Figure 1 page 476 for clarification.

As mentioned above, claim 1 recites "a distance between two electrodes of the probe … the said distance is about 6 mm to about 10 mm". There is no teaching, disclosure, or suggestion in Measurement to provide a probe having electrodes spaced at a distance of about 6 mm to about 10 mm. **Instead, Measurement teaches electrodes space at distances of 1.8 mm, 3.5 mm, and 5.3 mm.**

Additionally, applicants submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application). In particular, a combination of Campbell and Measurement does not provide for tissue edema measurement. Campbell does not disclose anything about measuring frequency, relation of capacitance or dielectric constant and water content, probe size or deeper water measurement (as described above). The article Measurement is theoretical study where so called three layer model and use of three different size probes are presented to calculate dielectric constant of subcutaneous fat (see abstract of "Measurement"). Hence the purpose of the "Measurement" is to describe a method how to measure dielectric constant of the subcutaneous fat itself and its combination with Campbell does not provide method to measure tissue edema. Neither Campbell nor the article "Measurement" mention anything about measuring edema.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed

invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. (see MPEP 2143.01, page 2100-98, column 1). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination (see MPEP 2143.01, page 2100-98, column 2). A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is **not sufficient** to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. (see MPEP 2143.01, page 2100-99, column 1) Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). >See also Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.)

In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide an electromagnetic probe that is placed on the skin during the measurement, and a capacitance of the probe is proportional to a dielectric constant of the skin and subcutaneous fat tissue, which is further proportional to a water content of the skin, and a distance between the two electrodes is about 6 mm to about 10 mm, as claimed in claim

1. The features of claim 1 are not disclosed or suggested in the art of record. Therefore, claim 1 is patentable and should be allowed.

Though dependent claims 2-6 contain their own allowable subject matter, these claims should at least be allowable due to their dependence from allowable claim 1. However, to expedite prosecution at this time, no further comment will be made.

Claim 7 was previously amended to claim "a high frequency unit for measuring the capacitance of the electromagnetic probe, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a first range of approximately 20-50 MHz, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a second range of approximately 50-500 MHz, wherein the first range corresponds to a measure of upper layers of the skin, and wherein the second range corresponds to a measure of deep layers of the skin **and the subcutaneous fat tissue** ... a distance between two electrodes of the probe being large enough ... to penetrate up to **and including** the subcutaneous fat tissue" [emphasis added].

It appears that the examiner did not address the previous claim amendment for claim 7 in the of office action dated 07/20/2010. The last amendment added language to claim 7 which recites features (see bold items above) not disclosed or suggested in the cited art. It appears that the examiner has not examined the language of previously amended claim 7 properly. For example, the examiner has not addressed the

language used in claim 7: "wherein the second range corresponds to a measure of deep layers of the skin **and the subcutaneous fat tissue** … a distance between two electrodes of the probe being large enough … to penetrate up to **and including** the subcutaneous fat tissue".

The examiner is directed to MPEP 707.07(f). As noted in MPEP 707.07(f) "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it". The examiner has not done this in this case. As noted in MPEP 707.07(f) "If a rejection of record is to be applied to a new or amended claim, specific identification of that ground of rejection, as by citation of the paragraph in the former Office letter in which the rejection was originally stated, should be given." The examiner has not done this in this case, for example see the rejection in the office action regarding claim 7.

Similar to the arguments presented above with respect to claim 1, Campbell fails to provide a teaching directed to measuring edema. Campbell does not disclose a device to measure tissue water content. Instead, Campbell teaches measuring skin surface hydration. Furthermore, there is no disclosure or suggestion of the capacitance of the probe as proportional to dielectric constant and water content of the skin. Additionally, the examiner admits that Campbell is silent as to the frequency used and the distance between the two electrodes of the probe.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. Additionally, the article Measurement does not disclose that a measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use of three probes is clear difference when comparing to the current application where is no reference to use different size of the probes at the same time. Furthermore, there is no mention in the article that these measurements are used to detect edema.

The article "Penetration" is directed to describing how the choice of measuring frequency affects on the measuring depth. The result is that at high frequencies (above 100 MHz) the open-ended coaxial probe measures the skin and subcutaneous tissue, and at lower frequencies (below 10 MHz) it measures mainly the superficial structures [see Conclusion, first paragraph, last sentence, p N174]. **There is no mention in the article that the method presented would be used to measure tissue edema.**

Neither Campbell, Measurement, nor Penetration teach or suggest a high frequency unit for measuring the capacitance of the electromagnetic probe, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a first range of approximately 20-50 MHz, wherein the

high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a second range of approximately 50-500 MHz, wherein the first range corresponds to a measure of upper layers of the skin, and wherein the second range corresponds to a measure of deep layers of the skin and the subcutaneous fat tissue … a distance between two electrodes of the probe being large enough … to penetrate up to and including the subcutaneous fat tissue, as claimed in applicants' claimed invention.

Additionally, applicants submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application). In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide for edema measurements, as **none of the documents mention of term edema or its measurement.** The features of claim 7 are not disclosed or suggested in the art of record. Therefore, claim 7 is patentable and should be allowed.

Though dependent claim 8 contains allowable subject matter, this claim should at least be allowable due to dependence from allowable claim 7. However, to expedite prosecution at this time, no further comment will be made.

Claim 12 clams an "attenuator connected between the oscillator and the power splitter, wherein attenuator is configured to prevent access of a signal reflected from the electromagnetic probe". The features of claim 12 are not disclosed or

suggested in the art of record. Therefore, claim 12 is patentable and should be allowed. Furthermore, claim 12 depends from claim 7 and thus includes all the limitations of claim 7. Thus, claim 12 is believed to be allowable for at least the reasons given for claim 7.

Claim 11 claims "placing an electromagnetic probe on the skin … transmitting a first portion of the first signal to the probe and through the skin and subcutaneous fat tissue … receiving a reflected signal from the skin and subcutaneous fat tissue through the probe … operating the phase detector in a saturated state, wherein signal amplitudes from the reflected signal and the second portion of the first signal form the saturated state … and calculating a water content of the skin based on the dielectric constant".

Malicki et al. discloses a reflectrometric moisture meter for capillary-porous materials, especially for the soil. The measuring is made by using oblong dagger-like electrodes inserted into the soil (see col. 2, lines 11-12). As mentioned in the title of the patent, this meter is for the measuring of soil. There is no mention or description of measuring of the edema or measuring the skin. Applicants further submit that **skin is not a capillary-porous material as described in patent of Malicki**. In particular, Malicki teaches that the meter "can be applied for any such capillary-porous material which allows introduction of the probe in a non-destructive way … [s]uch materials include: the soil, agricultural products (grain, hop cones, tobacco leaves, hay), food industry products (flour, bakery products), wood, moulding sand, subgrades, building foundations etc".

Similar to the arguments presented above with respect to claims 1 and 7, Campbell fails to provide a teaching directed to measuring edema. Campbell does not disclose a device to measure tissue water content. Instead, Campbell teaches measuring skin surface hydration. Furthermore, there is no disclosure or suggestion of the capacitance of the probe as proportional to dielectric constant and water content of the skin. Additionally, the examiner admits that Campbell is silent as to the frequency used and the distance between the two electrodes of the probe.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. Additionally, the article Measurement does not disclose that a measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use of three probes is clear difference when comparing to the current application where is no reference to use different size of the probes at the same time. Furthermore, there is no mention in the article that these measurements are used to detect edema.

The article "Penetration" is directed to describing how the choice of measuring frequency affects on the measuring depth. The result is that at high frequencies (above 100 MHz) the open-ended coaxial probe measures the skin and subcutaneous

tissue, and at lower frequencies (below 10 MHz) it measures mainly the superficial structures [see Conclusion, first paragraph, last sentence, p N174]. There is no mention in the article that the method presented would be used to measure tissue edema.

Neither Malicki, Campbell, Measurement, nor Penetration teach or suggest anything relating to measuring tissue edema.

Applicants submit that there is no disclosure or suggestion in the art of record of operating the phase detector in a saturated state. **Applicants again note that the examiner has not pointed out any prior art reading on this feature of the invention.** As noted in MPEP 707.07(f) "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it". The examiner has not done this in this case.

Applicants further submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application). For example, Malicki teaches that the oblong dagger-like electrodes 1a, 1b, 1c, have lengths of 0.1 m, 0.25 m, and 0.5 m (see col. 6, lines 64-68). These large electrodes are **inserted into the soil** and each spaced several meters from each other (see Fig. 1). There is no disclosure or suggestion in Malicki of inserting the oblong dagger-like electrodes into the skin of a person. Thus, it is clear that the teachings of Malicki are directed to industrial applications. Whereas, the

teachings of Campbell, Measurement, and Penetration are directed to measurements on human skin.

In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide the method as claimed in claim 11. The features of claim 11 are not disclosed or suggested in the art of record. Therefore, claim 11 is patentable and should be allowed.

Applicants also note that the article "Variational Formulation of …" (cited by the examiner) is a theoretical study where a mathematical model to take subcutaneous fat into account is presented when open-ended probe measurements on the skin are performed. Now term takes into account means that dielectric value of the skin can be measured without effect of subcutaneous fat on the measurement. Again there is no mention in the article that the method presented would be used to measure tissue edema.

Claims 13-19 have been added above to further claim the features recited therein.

For all of the foregoing reasons, it is respectfully submitted that all of the claims now present in the application are clearly novel and patentable over the prior art of record. Accordingly, favorable reconsideration and allowance is respectfully requested. If there are any additional charges with respect to this Amendment or otherwise, please charge deposit account 50-1924 for any fee deficiency. Should any

unresolved issue remain, the examiner is invited to call applicants' attorney at the telephone number indicated below.

Respectfully submitted,

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1/20/2011
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